

CLAIMS

We Claim:

1. A coating suspension comprising:
 - an osmopolymer;
 - an osmotic agent;
 - a film former, wherein the coating suspension includes from about 5 wt% to about 7 wt% of the film former; and
 - a two part solvent system.
2. The coating suspension of claim 1, wherein the total solids content of the coating suspension is from about 16 wt% to about 20 wt %.
3. The coating suspension of claim 1, wherein the total solids content of the coating suspension is from about 16 wt% to about 18 wt %.
4. The coating suspension of claim 1, wherein the total solids content of the coating suspension is about 16 wt%.
5. The coating suspension of claim 1, wherein the total solids content of the coating suspension is about 18 wt %.
6. The coating suspension of claim 1, wherein the total solids content of the coating suspension is about 20 wt%.
7. The coating suspension of claim 1, wherein the ratio of osmopolymer to osmotic agent included in the coating suspension is about 0.5:1 to about 0.7:1
8. The coating suspension of claim 1, wherein the ratio of osmopolymer to osmotic agent included in the coating suspension is about 0.6:1.

9 The coating suspension of claim 1, wherein the coating suspension includes about 5 wt% film former.

10. The coating suspension of claim 1, wherein the coating suspension includes about 6 wt% film former.

11. The coating suspension of claim 1, wherein the coating suspension includes about 7 wt% film former.

12. The coating suspension of claim 1, wherein the two part solvent system accounts for about 80 wt% to about 84 wt% of the coating suspension.

13. The coating suspension of claim 1, wherein the two part solvent system accounts for about 80 wt% to about 82 wt% of the coating suspension.

14. The coating suspension of claim 1, wherein the two part solvent system accounts for about 80 wt% of the coating suspension.

15. The coating suspension of claim 1, wherein the two part solvent system accounts for about 82 wt% of the coating suspension.

16. The coating suspension of claim 1, wherein the two part solvent system accounts for about 84wt% of the coating suspension.

17. The coating suspension of claim 1, wherein the osmopolymer, the osmotic agent, and the film former account for about 16 wt% to about 20 wt% of the coating suspension, with the coating suspension including about 5 wt% to about 7 wt% film former, about 3 wt% to about 6.2 wt% osmopolymer, and about 5.3% to about 10% osmotic agent.

18. The coating suspension of claim 17, wherein the two part solvent system accounts for about 80 wt% to about 84 wt% of the coating suspension.

19. The coating suspension of claim 18, wherein the two part solvent system includes an organic solvent and an aqueous solvent, wherein the organic solvent is miscible with the aqueous solvent and the osmopolymer is poorly soluble in the organic solvent.

20. The coating suspension of claim 18, wherein the two part solvent system comprises ethanol and water.

21. The coating suspension of claim 20, wherein the ratio of ethanol to water included in the two part solvent system is about 1:2 to about 1:4.

22. The coating suspension of claim 20, wherein the ratio of ethanol to water included in the two part solvent system is about 1:2.2 to about 1:3.5.

23. The coating suspension of claim 20, wherein the wherein the osmopolymer, the osmotic agent, and the film former account for about 16 wt% of the coating suspension, and the ratio of ethanol to water included in the two part solvent system is about 1:3 to about 1:3.5.

24. The coating suspension of claim 20, wherein the wherein the osmopolymer, the osmotic agent, and the film former account for about 20 wt% of the coating suspension, and the ratio of ethanol to water included in the two part solvent system is about 1:2 to about 1:2.2.

25. The coating suspension of claim 18, wherein the osmopolymer, the osmotic agent, and the film former account for about 16 wt% the coating suspension, with the coating suspension including about 5 wt% film former, about 3.7 wt% to about 4.5 wt% osmopolymer, and about 6.5 wt% to about 7.3 wt% osmotic agent.

26. The coating suspension of claim 18, wherein the osmopolymer, the osmotic agent, and the film former account for about 16 wt% the coating suspension, with the coating suspension including about 5 wt% film former, about 4.1 wt% osmopolymer, and about 6.9 wt% osmotic agent.

27. The coating suspension of claim 18, wherein the osmopolymer, the osmotic agent, and the film former account for about 16 wt% the coating suspension, with the coating suspension including about 6 wt% film former, about 3.3 wt% to about 4.1 wt% osmopolymer, and about 5.9 wt% to about 6.7 wt% osmotic agent.

28. The coating suspension of claim 18, wherein the osmopolymer, the osmotic agent, and the film former account for about 16 wt% the coating suspension, with the coating suspension including about 6 wt% film former, about 3.7 wt% osmopolymer, and about 6.3 wt% osmotic agent.

29. The coating suspension of claim 18, wherein the osmopolymer, the osmotic agent, and the film former account for about 16 wt% the coating suspension, with the coating suspension including about 7 wt% film former, about 3 wt% to about 3.7 wt% osmopolymer, and about 5.3 wt% to about 6 wt% osmotic agent.

30. The coating suspension of claim 18, wherein the osmopolymer, the osmotic agent, and the film former account for about 16 wt% the coating suspension, with the coating suspension including about 7 wt% film former, about 3.4 wt% osmopolymer, and about 5.6 wt% osmotic agent.

31. The coating suspension of claim 18, wherein the osmopolymer, the osmotic agent, and the film former account for about 18 wt% the coating suspension, with the coating

suspension including about 5 wt% film former, about 4.3 wt% to about 5.4 wt% osmopolymer, and about 7.6 wt% to about 8.7 wt% osmotic agent.

32. The coating suspension of claim 18, wherein the osmopolymer, the osmotic agent, and the film former account for about 18 wt% the coating suspension, with the coating suspension including about 5 wt% film former, about 4.9 wt% osmopolymer, and about 8.1 wt% osmotic agent.

33. The coating suspension of claim 18, wherein the osmopolymer, the osmotic agent, and the film former account for about 18 wt% the coating suspension, with the coating suspension including about 6 wt% film former, about 4 wt% to about 4.9 wt% osmopolymer, and about 7.1 wt% to about 8 wt% osmotic agent.

34. The coating suspension of claim 18, wherein the osmopolymer, the osmotic agent, and the film former account for about 18 wt% the coating suspension, with the coating suspension including about 6 wt% film former, about 4.5 wt% osmopolymer, and about 7.5 wt% osmotic agent.

35. The coating suspension of claim 18, wherein the osmopolymer, the osmotic agent, and the film former account for about 18 wt% the coating suspension, with the coating suspension including about 7 wt% film former, about 3.7 wt% to about 4.5 wt% osmopolymer, and about 6.5 wt% to about 7.3 wt% osmotic agent.

36. The coating suspension of claim 18, wherein the osmopolymer, the osmotic agent, and the film former account for about 18 wt% the coating suspension, with the coating suspension including about 7 wt% film former, about 4.1 wt% osmopolymer, and about 6.9 wt% osmotic agent.

37. The coating suspension of claim 18, wherein the osmopolymer, the osmotic agent, and the film former account for about 20 wt% the coating suspension, with the coating suspension including about 5 wt% film former, about 5 wt% to about 6.2 wt% osmopolymer, and about 8.8 wt% to about 10 wt% osmotic agent.

38. The coating suspension of claim 18, wherein the osmopolymer, the osmotic agent, and the film former account for about 20 wt% the coating suspension, with the coating suspension including about 5 wt% film former, about 5.6 wt% osmopolymer, and about 9.4 wt% osmotic agent.

39. The coating suspension of claim 18, wherein the osmopolymer, the osmotic agent, and the film former account for about 20 wt% the coating suspension, with the coating suspension including about 6 wt% film former, about 4.7 wt% to about 5.8 wt% osmopolymer, and about 8.2 wt% to about 9.3 wt% osmotic agent.

40. The coating suspension of claim 18, wherein the osmopolymer, the osmotic agent, and the film former account for about 20 wt% the coating suspension, with the coating suspension including about 6 wt% film former, about 5.3 wt% osmopolymer, and about 8.7 wt% osmotic agent.

41. The coating suspension of claim 18, wherein the osmopolymer, the osmotic agent, and the film former account for about 20 wt% the coating suspension, with the coating suspension including about 7 wt% film former, about 4.3 wt% to about 5.4 wt% osmopolymer, and about 7.6 wt% to about 8.7 wt% osmotic agent.

42. The coating suspension of claim 18, wherein the osmopolymer, the osmotic agent, and the film former account for about 20 wt% the coating suspension, with the coating

suspension including about 7 wt% film former, about 4.9 wt% osmopolymer, and about 8.1 wt% osmotic agent.

43. The coating suspension of claim 18, wherein the film former comprises a material selected from a group consisting of hydroxyethylcellulose, such as Natrasol, hydroxypropyl methylcellulose, methylcellulose, polyvinylalcohol-polyethylene glycol graft polymer, and polyvinyl-pyrrolidone polymers, such as Kollidone® 25, Kollidone® 30, and Kollidone® VA 64.

44. The coating suspension of claim 18, wherein the film former comprises hydroxyethylcellulose, such as Natrasol, the osmopolymer comprises NaCMC, and the osmotic agent comprises NaCl.

45. An osmotic coating comprising:

an osmopolymer;

an osmotic agent, with the osmopolymer and osmotic agent together accounting for about 55 wt% to about 76 wt% of the osmotic coating; and

a film former, with the film former accounting for about 25 wt% to about 44 wt% of the osmotic coating.

46. The osmotic coating of claim 45, wherein the osmotic coating comprises about 31.3 wt% to about 43.8 wt% of the film former.

47. The osmotic coating of claim 46, wherein the osmotic coating comprises about 31.3 wt % film former, about 22.9 wt% to about 28.3 wt% osmopolymer, and about 40.4 wt% to about 45.8 wt% osmotic agent.

48. The osmotic coating of claim 46, wherein the osmotic coating comprises about 37.5 wt% film former, about 20.8 wt% to about 25.7 wt% osmopolymer, and about 36.8 wt% to about 41.7 wt% osmotic agent.

49. The osmotic coating of claim 46, wherein the osmotic coating comprises about 43.8 wt% film former, about 18.7 wt% to about 23.1 wt% osmopolymer, and about 33.1 wt% to about 37.5 wt% osmotic agent.

50. The osmotic coating of claim 45, wherein the osmotic coating comprises about 27.8 wt% to about 41.2 wt% film former.

51. The osmotic coating of claim 50, wherein the osmotic coating comprises about 27.8 wt % film former, about 24.1 wt% to about 29.7 wt% osmopolymer, and about 42.5 wt% to about 48.1 wt% osmotic agent.

52. The osmotic coating of claim 50, wherein the osmotic coating comprises about 33.3 wt% film former, about 22.2 wt% to about 27.5 wt% osmopolymer, and about 39.2 wt% to about 44.5 wt% osmotic agent.

53. The osmotic coating of claim 50, wherein the osmotic coating comprises about 41.2 wt% film former, about 19.6 wt% to about 24.2 wt% osmopolymer, and about 34.6 wt% to about 39.2 wt% osmotic agent.

54. The osmotic coating of claim 45, wherein the osmotic coating comprises about 25 wt% to about 35% wt% film former.

55. The osmotic coating of claim 50, wherein the osmotic coating comprises about 25 wt % film former, about 25 wt% to about 30.9 wt% osmopolymer, and about 44.1 wt% to about 50 wt% osmotic agent.

56. The osmotic coating of claim 50, wherein the osmotic coating comprises about 30 wt% film former, about 23.3 wt% to about 28.8 wt% osmopolymer, and about 41.2 wt% to about 46.7 wt% osmotic agent.

57. The osmotic coating of claim 50, wherein the osmotic coating comprises about 35 wt% film former, about 21.7 wt% to about 26.8 wt% osmopolymer, and about 38.2 wt% to about 43.3 wt% osmotic agent.

58. The osmotic coating of claim 45, wherein the film former comprises a material selected from selected from a group consisting of hydroxyethylcellulose, such as Natrasol, hydroxypropyl methylcellulose, methylcellulose, polyvinylalcohol-polyethylene glycol graft polymer, and polyvinyl-pyrrolidone polymers, such as Kollidone® 25, Kollidone® 30, and Kollidone® VA 64.

59. The osmotic coating of claim 45, wherein the film former comprises hydroxyethylcellulose, such as Natrasol, the osmopolymer comprises NaCMC, and the osmotic agent comprises NaCl.

60. A controlled release dosage form, comprising:

an active agent formulation contained within a capsule;

an osmotic coating provided over the capsule, the osmotic coating comprising an osmopolymer, an osmotic agent, and a film former, with the osmopolymer and osmotic agent together accounting for about 55 wt% to about 76 wt% of the osmotic coating and the film former accounting for about 25 wt% to about 44 wt% of the osmotic coating;

a semipermeable layer; and

an optional barrier layer positioned between the capsule and the osmotic coating.

61. A method for providing an osmotic coating, the method comprising:
providing an intermediate dosage form;
providing a coating suspension comprising an osmopolymer, an osmotic agent, a film former, wherein the coating suspension includes from about 5 wt% to about 7 wt% of the film former, and a two part solvent system;
coating the intermediate dosage form with the coating suspension such that an the intermediate dosage form is coated with an osmotic coating.
62. The method according to claim 60, wherein said coating of the intermediate dosage form with the coating suspension is carried out under wet process conditions.
63. The method according to claim 60, wherein said coating of the intermediate dosage form is carried out under dry process conditions.